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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,075	06/25/2004	Mari Tabuchi	1422-0634PUS1	5317

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EXAMINER	
BALL, JOHN C	

ART UNIT	PAPER NUMBER
4128	

NOTIFICATION DATE	DELIVERY MODE
02/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/500,075	TABUCHI ET AL.	
	Examiner	Art Unit	
	J. CHRISTOPHER BALL	4128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☒ Claim(s) *1-5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :06/25/2004;03/01/2005;06/11/2007;07/09/2007.

DETAILED ACTION

Summary

1. This is the initial Office Action based on the TABUCHI et al. National Stage (371) application filed with the Office on June 25, 2004.

2. Claims 1-5 are currently pending and have been fully considered.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. JP 2001-400640, filed on December 28, 2001.

Specification

4. The use of the trademark MILLI-Q in the first full paragraph on page 6, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

   Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The disclosure is objected to because of the following informalities: the first sentence of the last paragraph appearing on page 5 is not grammatically correct. Appropriate correction is required.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

7. Claims 1-5 are objected to because of the following informalities: in claim 1 is recited the using water as a solution for preparing a sample. By itself, water does not constitute a solution, but is commonly used as a solvent in solutions. For examination purposes, not withstanding a persuasive argument to the contrary, the recitation of using water as a solution will be taken to mean utilization of water as a solvent to prepare the sample. Claims 2-5 are dependent on claim 1, and therefore also objected to for the reasoning stated above. Appropriate correction is required.

8. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in

proper dependent form, or rewrite the claim(s) in independent form. Use of water as a solvent to prepare a solution of the sample and subjecting a protein to electrophoresis recited in claim 1 is exactly the same as a protein dissolved in water being subjected to electrophoresis as recited in claim 2.

9. Claims 2-4 are objected to because of the following informalities: In each of the claims, the recitation of "a protein" with dependency of each claim back to claim 1, wherein is recited a protein, is ambiguous as to which protein. The antecedent basis for protein has been established in claim 1, and dependent claims should recited "the protein" or "said protein" to leave no question as to the protein in question is the protein recited in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a definition of a standard concentration to which one of the recited markers is to be adjusted to a concentration lower when compared. One of ordinary skill in the art would not

recognize an undefined standard concentration of a molecular weight marker for an electrophoresis separation.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by "Protocol for Resolving Protein Mixtures in Capillary Zone Electrophoresis", by GORDON et al. (ANALYTICAL CHEMISTRY, v63, n1, January 1, 1991, pp. 69-72.).

GORDON et al. discloses a protocol for resolving protein mixtures using capillary zone electrophoresis.

Regarding claims 1 and 2, GORDON et al. teaches preparation of a sample comprising proteins of interest in water (second sentence, first paragraph of "CZE Run Conditions", pg 70), for electrophoretic protein separations (remainder of the first paragraph of "CZE Run Conditions", pg 70). The proteins separated from the mixture in GORDON et al. (second paragraph of "CZE Run Conditions", pg 70) were not heat denatured in the stated protocol.

Regarding claim 5, GORDON et al. teaches the use of capillary zone electrophoresis as the method of electrophoresis.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Protocol for Resolving Protein Mixtures in Capillary Zone Electrophoresis", by GORDON et al. (ANALYTICAL CHEMISTRY, v63, n1, January 1, 1991, pp. 69-72.) in view of TADAYONI-REBEK et al. (U.S. Patent Application Publication 2002/0155455 A1).

GORDON et al. discloses the limitations recited in claim 1 as outlined in the 35 USC 102(b) rejection above.

GORDON et al. does not disclose molecular weight markers subject to electrophoresis together with a protein, as recited in claims 3 and 4.

However, TADAYONI-REBEK et al. disclose high homogeneous molecular markers for electrophoresis. TADAYONI-REBEK et al. teaches marker molecules comprising a collection of two or more marker molecules (paragraph [0019]), which is a limitation recited in claims 3 and 4. TADAYONI-REBEK et al. teaches the addition of the marker molecule composition to a sample containing protein (paragraph [0022]), which is a limitation recited in claim 3 and 4.

GORDON et al. and TADAYONI-REBEK et al. are analogous art in that they deal in the same technological area, electrophoretic separation of proteins.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the protocol of GORDON et al. with the utilization of molecular weight markers taught by TADAYONI-REBEK et al. because doing so allows one to obtain highly homogeneous visible molecular markers that are compatible with commercially available separation techniques (TADAYONI-REBEK et al., last sentence of paragraph [0011]).

Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention to try various concentrations of the molecular weight markers in the electrophoresis process. This would include adjusting the concentration of a molecular weight marker below a comparable standard concentration, as recited in claim 3; or adjusting the concentration of a molecular weight marker to some level between 0.1 and 10 times the concentration of the

protein being tested, as recited in claim 4. Adjusting the concentration level of reagents, including molecular weight markers, would be obvious for one of ordinary skill in the art to attempt in an effort to optimize the electrophoresis separation. See MPEP 2144.05 (II).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara Gilliam can be reached on (571) 272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara L. Gilliam/
Supervisory Patent Examiner, Art Unit 4128

JCB
02/06/2008